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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,753	05/13/2005	Pandurang Balwant Deshpande	123561	9152

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OLIFF & BERRIDGE, PLC  
P.O. BOX 19928  
ALEXANDRIA, VA 22320

EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/532,753

Applicant(s)

DESHPANDE ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 11, 13, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 5, 10, 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Golzález is noted but is not prior art to claim 9 because claim 9 is entitled to the 2/26/2003 priority date.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by 6878827, 6350869, and 4559334/4935507.

In 6878827, note publication date of 6/13/2002. See reference example 1-(3). The reference is silent on whether the material is amorphous or whether it is a monohydrate.

In 6350869, see example 2, the monohydrate. The reference is silent on whether the material is amorphous.

In 4559334, see Examples 14 and 16, material which 4935507 says is "crystalline like amorphous product" (column 1, lines 27-28) meaning "an amorphous material" which is "not a crystalline product" but what presumably only looked like a crystalline product. Thus, 4935507 is cited as a supplemental reference to explain the nature of the material in 4559334.

In summary, one reference is a monohydrate, but silent on amorphous, one reference is amorphous, but silent on monohydrate, and one reference is silent on both.

MPEP 2112 states:

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**“SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE  
DISCOVERY OF A NEW PROPERTY**

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”

In this case, the “unknown property” is the particular form (amorphous form, form of a hydrate, or both). This is unknown because the reference is silent on this property.

MPEP 2112 goes on to state:

**“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR  
ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS  
SILENT AS TO AN INHERENT CHARACTERISTIC**

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is silent on is the particular form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2<sup>nd</sup> 1241 at 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part

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determined by the precise process used in its manufacture.” (page 1253). The “properties” branch of that statement applies here.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, or ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

The traverse is unpersuasive. Applicants state, “Therefore, any showing that there exists a crystalline form of cefdinir with the same structural formula as recited in claims 15 and 16 would prove that the characteristic of being “amorphous” is not an inherent property.” This is confused. First, as noted above, this is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Second, even if it were, the question is whether e.g. 6350869 inherently produces amorphous material, not what some other process produces. If some other process produces crystalline material, that does not detract from what 6350869 has. In other words, if 6350869 inherently produces amorphous material, then amorphous material is old, it is in the public domain, and it cannot be patented. If applicants were to obtain a patent on such a material, the public would not be able to practice 6350869 even when the patent expires.

Applicants other argument is that, basically, they have two processes for making the amorphous material ("The amorphous form of cefdinir monohydrate is obtained either by adjusting the pH to acidic condition at 10°C to 40°C followed by rapid cooling to -10°C to -40°C, or by cooling the reaction mass to -40°C to 0°C followed by rapid addition of acid to lower the pH.") and that "None of the cited references per se follow these methods." This is illogical. It assumes that these are the only two methods of producing the material, but applicants present no evidence at all for such an assertion. Similarly, applicants argue more generally, "Those skilled in the art would appreciate that the nature of crystallization of any active pharmaceutical ingredient (API) depends on the temperature and/or mode of pH adjustment during crystallization." This simply is untrue. Temperature and "mode of pH adjustment" are by no means at all the only ways to adjust whether or not one gets an amorphous form.

To refute this, the examiner points to 6384213, which shows that one obtains for cefuroxime axetil a more amorphous material by changing the speed at which the water is added, or alternatively by using larger amounts of water. US 6294669 B1 shows that for Cefditoren pivoxyl, one can obtain the crystalline form by use of seeding. 5847118 teaches that one can get amorphous cefuroxime axetil by using very highly polar solvents, or using a small amount of water with the organic solvent. Other examples could be given as well. There is no logical basis for saying that just because e.g. 6350869 did not use applicants particular combination of temperature and pH adjustment methods that the amorphous product was not obtained.

With regard to the product-by-process limitation in claim 16, such does not distinguish over the prior art. A rejection is proper over a prior art reference which shows

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the same product, even if made by a different process. See: *In re Thorpe*, 227 USPQ 964; *In re Hirao*, 190 USPQ 15 (see footnote 3); *Ex parte Edwards*, 231 USPQ 981; *In re Pilkington*, 162 USPQ 145, 147; *In re Dilnot*, 133 USPQ 289.

Attention is called to 20060111566. The reference is not prior art. It appears to have the same process as claim 1. Claim 14 no longer conflicts as claim 14 is now limited to the N and K salts.

Attention is called to 20060069079 and 20060029674. It is not clear whether this amorphous material is a monohydrate or not. The references are not prior art.

Attention is called to WO 2006010978 A1, example 7. It is not clear whether this amorphous material is a monohydrate or not. The reference is not prior art. Note WO 2006006040 A2, example 9.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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1. The term "ester functional group" in claim 2 is of unknown meaning. A carboxylic acid is of form  $AC(O)OB$ . There are five possibilities as to this "ester functional group": a) removal of H from A to give  $-AC(O)OB$ , b) removal of H from B to give  $AC(O)OB^-$ , c) cleaving the acid to give the acyl piece, i.e.  $AC(O)^-$ , d) cleaving the acid to give the alcohol piece, i.e.  $BO^-$ , and e) cleaving the acid to give the acyloxy piece, i.e.  $AC(O)O^-$ . If the ester is not a carboxylic acid ester, e.g. is  $AS(O)_2OB$ , then other pieces such as  $AS(O)_2O^-$  or  $AS(O)_2^-$  are possible.
2. The claim 3 names with "...diammonium..." in them are not correct. M is clearly a mono-cation. Yet, these names would have two such nitrogens.

Claims 1-4, 6-8, 11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 1-4, 6-8, the specification, page 6, line 11 says that the acylation step is done in an "organic solvent". Water is listed on page 9, line 17, and hence applicants are entitled to that solvent as well, but nothing beyond that. Thus, solvents such as concentrated HCl, thionyl chloride, HF, sulfuric acid, aqueous ammonia, and liquid sulfur dioxide are now embraced, but these are not organic solvents.

With regard to claims 11 and 13, see page 8, line 11, which again says that the dissolving is to be done in an organic solvent. The same problem arises.



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*Claim Objections*

Claim 1 has underscoring without text. The purpose here is unclear. Do applicants want these lines printed?

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

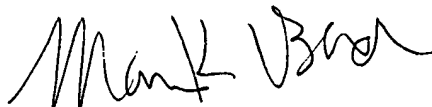
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Berch  
Primary Examiner  
Art Unit 1624

11/1/2006